MAR 2 8 2014

K133116

510(k) Summary as required by section 21 CFR 807.92(c)

21 CFR 807.92(a)(1)	
Submitter Name:	ConMed Corporation Viking Systems
Submitter Address:	525 French Road Utica, NY 13502
Contact Person:	Nancy J Gertlar. Quality Assurance and Regulatory Affairs
Telephone Number:	509-496-2248
Fax Number:	508-948-8070
Date of Preparation:	March 18, 2014
21 CFR 8007.92(a)(2)	
Device Trade Name:	VP1003 Video Extended Length Tray (RADEL) VP1005 Video Tray Single Level (RADEL) VP1006 Video Arthroscope Tray (RADEL) VP1007 Video Laparoscope Tray (RADEL)
Common Name:	Sterilization Container
Classification Name:	Sterilization Wrap Containers, Trays, Cassettes and Other Accessories
Classification Class:	Class II
Regulation:	21 CFR 880.6850
Product Code:	KCT
21 CFR 807.92(a)(3)	
Predicate Device:	Olympus MAJ-172 Instrument Tray for LTF Videoscope
Company Name:	KeyMed (Medical and Industrial Ltd)
510(k) Number:	K122818

807.92(a)(4)

Device Description:

VP1003 Video Extended Length Tray (RADEL)
VP1005 Video Tray Single Level (RADEL)
VP1006 Video Arthroscope Tray (RADEL)
VP1007 Video Laparoscope Tray (RADEL)

VP1003 Video Extended Length Tray (RADEL), VP1005 Video Tray Single Level (RADEL), VP1006 Video Arthroscope Tray (RADEL) and VP1007 Video Laparoscope Tray (RADEL) - are constructed of RADEL with perforations to facilitate steam sterilant penetration, evacuation and drying. These trays are designed to fit any standard autoclave and are manufactured from durable, biocompatible materials that are corrosion resistant and compatible with the environment of repeated steam sterilization. Since the trays are perforated, an FDA cleared sterilization wrap K082177 must be used to maintain sterility of the contents. Interior structures of the trays have the ability to separately hold individual instruments during the entire duration they are in contact with the tray. Although these trays are reusable they will not be serviced or repaired.

VP1003 Video Extended Length Tray (RADEL), VP1005 Video Tray Single Level (Tray), VP1006 Video Arthroscope Tray (RADEL) and VP1007 Video Laparoscope Tray (RADEL) - were designed in accordance with 21 CFR 820.30

Statement of Indication for Use
510(k) Number: K133116

Subject Device Names

VP1003 Video Extended Length Tray (RADEL)
VP1005 Video Tray Single Level (RADEL)
VP1006 Video Arthroscope Tray (RADEL)
VP1007 Video Laparoscope Tray (RADEL)

The Video Trays listed above are used for loading surgical instruments in or to conveniently organize, sterilize, transport and store the instruments between uses. The Video Trays listed above are not intended to maintain sterility; they are intended to be used in conjunction with a validated FDA cleared sterilization wrap in order to maintain sterility of the enclosed medical instruments.

The Video Trays listed above are intended to be used to enclose ConMed medical devices including hand instruments, trocars, camera heads, adapters, endoscopes, light guides, and bridge systems to steam sterilize the enclosed medical devices by a health care provider.

The instrument trays were validated as per below sterilization parameters:
Steam (wrapped) sterilization
Pre-vacuum cycle at 270 F (132 °C) for 4 minutes
Cool down to 48°C for 118 minutes

VP1003 Video Extended Length Tray (RADEL) dry cycle is 35 minutes. ConMed Corporation instruments which can be sterilized in this tray are scopes with an outer diameter not less than 5.5mm or greater than 10mm with lengths no greater than 530mm, and light guides with a length no greater than 10ft.

VP1005 Video Tray Single Level (RADEL) dry cycle is 40 minutes. ConMed Corporation instruments which can be sterilized in this tray are Scopes, Sheaths, Cannulas and Bridge System with internal diameters not less than 2.3mm, outer diameter not less than 2.9mm or greater than 10mm, and with lengths no greater than 404mm. Non-Cannulated, Non-Porous instruments with outer diameters not less than 2.9mm or greater than 3.2mm and with lengths no greater than 404mm may also be sterilized in this tray.

VP1006 Video Arthroscope Tray (RADEL) dry cycle is 20 minutes. ConMed Corporation instruments which can be sterilized in this tray are scopes with diameters not less than 2.9mm or greater than 4mm, with lengths no greater than 233mm.

VP1007 Video Laparoscope Tray (RADEL) dry cycle is 25 minutes. ConMed Corporation instruments which can be sterilized in this tray are scopes with diameters not less than 5.5mm or greater than 10mm. with lengths no greater than 404mm.

For additional instrument trays specifications refer to the table below.

Model Name	VP1003 Video Extended Length Tray (RADEL)	VP1005 Video Tray Single Level (RADEL)	VP1006 Video Arthroscope Tray (RADEL)	VP1007 Video Laparoscope Tray (RADEL)
Method	Steam (Wrapped)	Steam (Wrapped)	Steam (Wrapped)	Steam (Wrapped)
Cycle	Pre-vacuum	Pre-vacuum	Pre-vacuum	Pre-vacuum
Temperature	270F (132°C)	270F (132°C)	270F (132°C)	270F (132°C)
Exposure	4 minutes	4 minutes	4 minutes	4 minutes
Dry Cycle	35 minutes	40 minutes	20 minutes	25 minutes
Cool Down to 48°C	118 minutes	118 minutes	118 minutes	118 minutes
Maximum Load	3.9lbs (1.8kg)	8.0lbs (3.6kg)	1.1 lbs (0.5kg)	1.7 lbs (0.8kg)
Maximum Density	0.069lb/in3 (1.91gm/cm3)	0.094lb/in3 (2.60gm/cm3)	0.064 lb/in3 (1.77 gm/cm3)	0.077 lb/in3 (2.13gm/cm3)
Base	22.441 Length x 6.923 Width x 1.695 Height	20.901 Length x 9.715 Width x 2.045 Height	12.110 Length x 3.150 Width x 1.615 Height	17.253 Length x 3.158 Width x 1.615 Height
Lid	22.486 Length x 7.000 Width x .910 Height	20.921 Length x 9.760 Width x 1.52 Height	12.615 Length x 3.225 Width x .75 Height	17.295 Length x 3.220 Width x .750 Height
Assembled Unit	23 Length x 7.4 Width x 2.2 Height	21.5 Length x 10.2 Width x 3.2 Height	12.7 Length x 3.6 Width x 2.0 Height	17.8 Length x 3.6 Width x 2.0 Height
Stainless Steel Handles	2	2	N/A	N/A
Base Material	RADEL R-5100, Color Blue (PMS 300)	RADEL R-5100, Color Blue (PMS 300)	RADEL R-5100, Color Blue (PMS 300)	RADEL R-5100, Color Blue (PMS 300)
Hardware	Stainless Steel	Stainless Steel	Stainless Steel	Stainless Steel
Brackets	Silicone	Silicone	Silicone	Silicone
Graphics	Laser Etched	Laser Etched	Laser Etched	Laser Etched
Lid Material	RADEL R-5000, Color Smoke	RADEL R-5000, Color Smoke	RADEL R-5000, Color Smoke	RADEL R-5000, Color Smoke
Graphics	Silk Screen, White	Silk Screen, White	Silk Screen, White	Silk Screen, White

CONMED CORPORATION

21 CFR 807.92(a)(5)

Summary of Testing:

All model numbers included in K133116 were tested in accordance with Risk Management, Steam Sterilization Qualification, Cleaning Validation, Transportation Qualification, Verification of Report Handle Weight, and the Application of ISO 10883 and FDA #G95-1 in the Biological Evaluation of Video Trays. The protocols of all the listed tests were successfully completed.

Comparison to the Predicate Devices:

All model numbers included in K133116 were compared to the predicate device by review of the intended use and technological characteristics – product design, device characteristics and materials. Please refer to the Comparison Table for Substantial Equivalence on the following pages.

Substantial Equivalence Discussion:

All model numbers included in K133116 were found to be substantially equivalent based on the same intended use and side by side comparison of technological characteristics. The predicate is cleared for steam and ETO. The model numbers in K133116 are claiming steam sterilization only. This does not create any new risks or hazards.

Verifications regarding this 510(k) Summary:

The summary includes only information that is also covered in the body of the 510(k). The summary does not contain any raw data, i.e., contains only summary data. The summary does not contain trade secret or confidential commercial information. The summary does not contain any patient identification information.

21 CFR 807.92 (b)(c)

Substantial Equivalence Conclusion:

It is concluded that the models numbers listed above, are substantially equivalent, based on the non clinical testing (discussed above) that demonstrates that the device is as safe and effective as the predicate device.

21 CFR 807.92 (a)(6)

Comparison Table for Substantial Equivalence Table 1

510(k) Number	K133116	K122818
Proprietary Name	VP1003 Video Extended Length Tray (RADEL), VP1005 Video Tray Single Level (RADEL), VP1006 Video Arthroscope Tray (RADEL), VP1007 Video Laparoscope Tray (RADEL)	Olympus MAJ-172 Instrument Tray for LTF Videoscope
Original Applicant Name	ConMed Corporation Viking Systems Utica, NY	Olympus KeyMed, San Diego, CA
Submitter	ConMed Corporation Viking Systems Utica, NY	KeyMed Essex UK
Regulation Number	21 CFR 880.6850	21 CFR 880.6850
Class	II	II
Product Code	KCT	KCT
Decision Date	Pending	January 4, 2013
Common/Usual Name	Sterilization Container	Sterilization Container
Classification Name	Sterilization wrap, containers, trays, cassettes and other accessories	Sterilization wrap, containers, trays, cassettes and other accessories
Predicate Device	K122818	K033222
Target Populations	Health Care Provider	Health Care Provider
Design	Perforated tray and lid	Perforated tray and lid
Sterilization Wrap	K082177	Not stated in the summary

21 CFR 807.92 (a) (6)

Comparison Table for Substantial Equivalence Table 2

K133116 Model Numbers	K122818	Differences
VP1003 Video Extended Length Tray (RADEL) VP1005 Video Tray Single Level (RADEL) VP1006 Video Arthroscope Tray (RADEL) VP1007 Video Laparoscope Tray (RADEL)	KeyMed Olympus MAJ-172 Instrument Tray for LTF Videoscope	
The model numbers listed above are intended to be used to enclose ConMed medical devices including hand instruments, trocars, camera heads, adapters, endoscopes, light guides, and bridge systems to steam sterilize the enclosed medical devices by a health care provider.	The Olympus MAJ-172 Instrument Tray for LTF Videoscopes is intended to be used to enclose Olympus medical devices including hand instruments, trocars, camera heads, adapters, and endoscopes to be sterilized by a health care provider.	The only difference is ConMed product vs Olympus product.
	It is intended to allow steam or ethylene oxide sterilization of the enclosed medical device.	K133116 is steam only
The model numbers listed above are used for loading surgical instruments in or to conveniently organize, sterilize, and transport and store the instruments between uses.	The Olympus MAJ-172 Instrument Tray for LTF Videoscope is designed to secure and store a single videoscope and its accessories for sterilization at a healthcare facility.	K122818 is only for one videoscope and accessories. K133116 is for multiple ConMed products and accessories.
VP1003 Video Extended Length Tray (RADEL). Method: Steam (Wrapped); Cycle: Pre-vacuum; Temperature: 270degF (132degC); Exposure: 4 minutes; Dry Cycle: 35	Steam Sterilization: Vacuum: 0.016 MPa minimum Pressure: 0.101 MPa minimum Temperature: 135 deg C Exposure Time: 3 minutes	K133116 Temp 132degC Exposure 4 min Dry 35 min K122818 Temp 135degC Exposure 3 min

minutes; Maximum Load: 3.9lbs (1.8kg); Maximum Density: 0.069lb/in3 (1.91gm/cm3)	Drying Time: 20 minutes	Dry 20 min
VP1005 Video Tray Single Level (RADEL), Method: Steam (Wrapped); Cycle: Pre-vacuum; Temperature: 270degF (132degC); Exposure: 4 minutes; Dry Cycle: 40 minutes; Maximum Load: 8.0lbs (3.6kg); Maximum Density: 0.094lb/in3 (2.60gm/cm3)	Steam Sterilization: Vacuum: 0.016 MPa minimum Pressure: 0.101 MPa minimum Temperature: 135 deg C Exposure Time: 3 minutes Drying Time: 20 minutes	K133116 Temp 132degC Exposure 4 min Dry 40 min K122818 Temp 135degC Exposure 3 min Dry 20 min
VP1006 Video Arthroscope Tray (RADEL), Method: Steam (Wrapped); Cycle: Pre-vacuum; Temperature: 270degF (132degC); Exposure: 4 minutes; Dry Cycle: 15 minutes; Maximum Load: 1.1lbs (0.5kg); Maximum Density: 0.064lb/in3 (1.77gm/cm3)	Steam Sterilization: Vacuum: 0.016 MPa minimum Pressure: 0.101 MPa minimum Temperature: 135 deg C Exposure Time: 3 minutes Drying Time: 20 minutes	K133116 Temp 132degC Exposure 4 min Dry 15 min K122818 Temp 135degC Exposure 3 min Dry 20 min
VP1007 Video Laparoscope Tray (RADEL), Method: Steam (Wrapped); Cycle: Pre-vacuum; Temperature: 270degF (132degC); Exp: 4 minutes; Dry Cycle: 25 minutes; Maximum Load: 1.7lbs (0.8kg); Max Density: 0.077lb/in3 (2.13gm/cm).	Steam Sterilization: Vacuum: 0.016 MPa minimum Pressure: 0.101 MPa minimum Temperature: 135 deg C Exposure Time: 3 minutes Drying Time: 20 minutes	K133116 Temp 132degC Exposure 4 min Dry 25 min K122818 Temp 135degC Exposure 3 min Dry 20 min

21 CFR 807.92 (b) (1)

Comparison Table for Substantial Equivalence Table 3

	K133116	K122818
Standards Met	ST77 Containment devices for reusable medical device sterilization	Not stated in the summary
	ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process"	Not stated in the summary
	FDA #G95-1 "Use of International Standards Series 10993-1:2009/Cor1:2010"	Not stated in the summary
Materials	RADEL	RADEL
Biocompatibility	ISO 10993-1:2009/Cor1:2010	Not stated in the summary
Sterility	The device is sold non sterile	The device is sold non sterile
Cleaning Studies	ConMed Report CL227 Cleaning Validation	Not stated in the summary
Environmental Studies	ConMed Report TR13-390 Verification Report Handle Weight Requirement ANSI/AAMI ST77:2006	Not stated in the summary
Transportation Studies	ConMed Report TR13-050 Transportation Qualification	Simulated tests included use tests, drop testing resistance to chemical, cleaning, steam sterilization
Electrical Safety	N/A	N/A
Mechanical Safety	N/A	N/A
Chemical Safety	N/A	N/A
Thermal Safety	N/A	N/A
Radiation Safety	N/A	N/A

21 CFR 807.92 (b)(3)

Summary of Non Clinical Tests

TR13-707 Risk Management Report	Conclusion: Throughout the design process, various mitigations and control methods have been identified and applied to the device(s), including safety mechanisms that address concerns identified in relevant post-market surveillance. These have been verified or validated to demonstrate that the risks have been reduced as far as reasonably practicable and the device(s) perform as intended by the established design requirements. This report confirms that the Risk Management Plan has been appropriately implemented and that methods are in place to obtain relevant production and post-production information. The risks associated with the use of these devices constitute acceptable risks when weighed against the benefits to the patient and are compatible with high level of protection of health and safety. It has been determined that the overall residual risk is acceptable.
TR12-343 Steam Sterilization Qualification VP1003 Video Extended Length Tray	Conclusion: Results of the three half cycles demonstrate the tested cycle imparts sufficient lethality to produce an SAL of 10-6 at twice the half cycle exposure duration (full cycle) when the full tray is sterilized in accordance with the cycle type, temperature, exposure time, configuration and placement within the chamber tested in this study. All acceptance criteria defined in the ConMed Lab Study LS13S-007 Protocol were met.
TR12-345 Steam Sterilization Qualification VP1005 Video Tray Single Level	Conclusion: Results of the three half cycles demonstrate the tested cycle imparts sufficient lethality to produce an SAL of 10-6 at twice the half cycle exposure duration (full cycle) when the full tray is sterilized in accordance with the cycle type, temperature, exposure time, configuration and placement within the chamber tested in this study. All acceptance criteria defined in the ConMed Lab Study LS13S-010 Protocol were met.
TR12-346 Steam Sterilization Qualification VP1006 Video Arthroscope Tray	Conclusion: Results of the three half cycles demonstrate the tested cycle imparts sufficient lethality to produce an SAL of 10-6 at twice the half cycle exposure duration (full cycle) when the full tray is sterilized in accordance with the cycle type, temperature, exposure time, configuration and placement within the chamber tested in this study. All acceptance criteria defined in the ConMed Lab Study LS13S-008 Protocol were met.
TR12-347 Steam Sterilization Qualification	Conclusion: Results of the three half cycles demonstrate the tested cycle imparts sufficient lethality to produce an SAL of 10-6 at twice the half cycle exposure duration (full cycle) when the full tray is sterilized in accordance with the cycle type, temperature, exposure time, configuration and placement within the chamber tested in this study.

VP1007 Video Laparoscope Tray	All acceptance criteria defined in the ConMed Lab Study LS13S-009 Protocol were met.
TR13-121 Cleaning Validation	Conclusion: Devices tested meet specifications for acceptance. The manual cleaning using a soft bristled brush and mild neutral pH detergent to clean all surfaces described in the cleaning method. This cleaning method is validated for VP1003 Video Extended Length Tray VP1005 Video Tray Single Level VP1006 Video Arthroscope Tray VP1007 Video Laparoscope Tray
TR13-050 Transportation Qualification	Conclusion: The results of this study support the Transportation and Distribution Storage Qualification of the trays. The results of the qualification demonstrate that the non sterile product and packaging maintained physical properties and characteristics for intend use after transportation conditioning.
TR13-390 Verification Report Handle Weight Requirement	Conclusion: The handle load requirements of ANSI/AAMI ST77:2006, Section 4.3.6.4 (b) are met. The test trays met the requirement of withstanding a 32 pound force without breaking free from the tray or permanently cracking or deforming.
TR14-027	This report documents the successful validation of the 118 minute cool down time for the VP1003 Video Extended Length Tray (RADEL), VP1005 Video Tray Single Level (RADEL), VP1006 Video Arthroscope Tray (RADEL) and VP1007 Video Laparoscope Tray (RADEL).
TR13-517 Application of ISO 10993 and FDA #G95-1 in the Biological Evaluation of Video Trays	Conclusion: The materials used in the Video Trays have been tested and have demonstrated an acceptable biocompatibility profile for its intended use. It can be concluded that use of the Video Trays does not pose a biological safety risk as identified in the Preliminary Hazard Analysis. Based on these comprehensive tests, the benefits of the materials for the intended use outweigh the clinical risks. In conclusion, it was demonstrated that these devices meet the biological evaluation requirements of ISO 10993-1:2009 and FDA #G95-1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 28, 2014

ConMed Corporation Viking Systems
Ms. Nancy J. Gertlar
Quality Assurance and Regulatory Affairs
525 French Road
Utica, NY 13502

Re: K133116
Trade/Device Name: VP1003 Video Extended Length Tray (RADEL)
VP1005 Video Tray Single Level (RADEL)
VPI 006 Video Arthroscope Tray (RADEL)
VP1007 Video Laparoscope Tray (RADEL)
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap Containers, Trays Cassettes and Other Accessories
Regulatory Class: II
Product Code: KCT
Dated: March 18, 2014
Received: March 20, 2014

Dear Ms. Gertlar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: **K133116**

Subject Device Names

VP1003 Video Extended Length Tray (RADEL)
VP1005 Video Tray Single Level (RADEL)
VP1006 Video Arthroscope Tray (RADEL)
VP1007 Video Laparoscope Tray (RADEL)

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The Video Trays listed above are intended to be used to enclose ConMed medical devices including hand instruments, trocars, camera heads, adapters, endoscopes, light guides, and bridge systems to steam sterilize the enclosed medical devices by a health care provider.

The instrument trays were validated as per below sterilization parameters:
Steam (wrapped) sterilization
Pre-vacuum cycle at 270 F (132 °C) for 4 minutes
Cool down to 48°C for 118 minutes

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VP1005 Video Tray Single Level (RADEL) dry cycle is 40 minutes. ConMed Corporation instruments which can be sterilized in this tray are Scopes, Sheaths, Cannulas and Bridge System with internal diameters not less than 2.3mm, outer diameter not less than 2.9mm or greater than 10mm, and with lengths no greater than 404mm. Non-Cannulated, Non-Porous instruments with outer diameters not less than 2.9mm or greater than 3.2mm and with lengths no greater than 404mm may also be sterilized in this tray.

VP1006 Video Arthroscope Tray (RADEL) dry cycle is 20 minutes. ConMed Corporation instruments which can be sterilized in this tray are scopes with diameters not less than 2.9mm or greater than 4mm, with lengths no greater than 233mm.

VP1007 Video Laparoscope Tray (RADEL) dry cycle is 25 minutes. ConMed Corporation instruments which can be sterilized in this tray are scopes with diameters not less than 5.5mm or greater than 10mm, with lengths no greater than 404mm.

Indications for Use Statement

For additional instrument trays specifications refer to the table below.

Model Name	VP1003 Video Extended Length Tray (RADEL)	VP1005 Video Tray Single Level (RADEL)	VP1006 Video Arthroscope Tray (RADEL)	VP1007 Video Laparoscope Tray (RADEL)
Method	Steam (Wrapped)	Steam (Wrapped)	Steam (Wrapped)	Steam (Wrapped)
Cycle	Pre-vacuum	Pre-vacuum	Pre-vacuum	Pre-vacuum
Temperature	270F (132°C)	270F (132°C)	270F (132°C)	270F (132°C)
Exposure	4 minutes	4 minutes	4 minutes	4 minutes
Dry Cycle	35 minutes	40 minutes	20 minutes	25 minutes
Cool Down to 48°C	118 minutes	118 minutes	118 minutes	118 minutes
Maximum Load	3.9lbs (1.8kg)	8.0lbs (3.6kg)	1.1 lbs (0.5kg)	1.7 lbs (0.8kg)
Maximum Density	0.069lb/in3 (1.91gm/cm3)	0.094lb/in3 (2.60gm/cm3)	0.064 lb/in3 (1.77 gm/cm3)	0.077 lb/in3 (2.13gm/cm3)
Base	22.441 Length x 6.923 Width x 1.695 Height	20.901 Length x 9.715 Width x 2.045 Height	12.110 Length x 3.150 Width x 1.615 Height	17.253 Length x 3.158 Width x 1.615 Height
Lid	22.486 Length x 7.000 Width x .910 Height	20.921 Length x 9.760 Width x 1.52 Height	12.615 Length x 3.225 Width x .75 Height	17.295 Length x 3.220 Width x .750 Height
Assembled Unit	23 Length x 7.4 Width x 2.2 Height	21.5 Length x 10.2 Width x 3.2 Height	12.7 Length x 3.6 Width x 2.0 Height	17.8 Length x 3.6 Width x 2.0 Height
Stainless Steel Handles	2	2	N/A	N/A
Base Material	RADEL R-5100. Color Blue (PMS 300)	RADEL R-5100. Color Blue (PMS 300)	RADEL R-5100. Color Blue (PMS 300)	RADEL R-5100. Color Blue (PMS 300)
Hardware	Stainless Steel	Stainless Steel	Stainless Steel	Stainless Steel
Brackets	Silicone	Silicone	Silicone	Silicone
Graphics	Laser Etched	Laser Etched	Laser Etched	Laser Etched
Lid Material	RADEL R-5000. Color Smoke	RADEL R-5000. Color Smoke	RADEL R-5000. Color Smoke	RADEL R-5000. Color Smoke
Graphics	Silk Screen. White	Silk Screen. White	Silk Screen. White	Silk Screen. White

Prescription Use___ AND/OR (Part 21 CFR 801 Subpart D)

Over-the-Counter Use_X_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
Susan Runner DDS, MA 2014.03.26
13:10:08 -04'00'